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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/664,008

09/16/2003

Benedikt Sas

4532680/16900 (KEM 69)

3907

26386

7590

01/28/2010

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215 10TH STREET SUITE 1300  
DES MOINES, IA 50309

EXAMINER

WANG, SHENGJUN

ART UNIT

PAPER NUMBER

1627

MAIL DATE

DELIVERY MODE

01/28/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/664,008	<b>Applicant(s)</b> SAS ET AL.	
	<b>Examiner</b> Shengjun Wang	<b>Art Unit</b> 1627	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 November 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 and 10 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

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### DETAILEDACION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 12, 2009 has been entered.

### *Claim Rejections 35 U.S.C. 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-3, 5-7 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 1 recites an expression "*hepatitis C infections caused by Flaviviridae sp.*" The expression is confusing in that it is not clear as to the scope of the hepatitis C infections caused by Flaviviridae. Is there species other than hepatitis C virus causing hepatitis C infection, or the claim defines that any infection caused by Flaviviridae as hepatitis C infection?

5. Claims 2 and 6, depending on claim 1, recite analogs of artemisinin. Note, the all the compounds encompassed by the general formula in claim 1 are artemisinin (Q is CO) and its analogs (Q is the others recited in claim 1). It is unclear if the "analogs" herein has: the same scope as defined in claim 1, a narrower scope than that in claim 1, or a broader scope than that in claim 1, i.e., a scope including any artemisinin derivatives?

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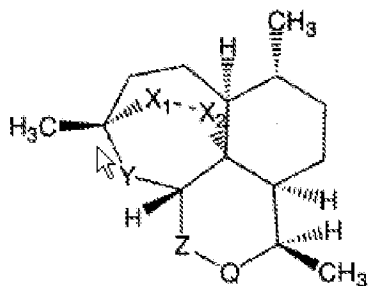
***Response to the Arguments***

Applicants' amendments and remarks submitted November 12, 2009 have been fully considered, and are found persuasive with respect to the rejections set forth in the prior office action. Particularly, artemisinin and the derivatives herein are particularly effective against BVDV in an in vitro model, but are not effective against several other viruses. The in vitro model is an art recognized model for HCV. See pages 6-7 of this application. In view of the unpredictability in the art, and the particular effective of artemisinin and its derivatives herein against BVDV. The claimed method of treating HCV infection would have not been obvious over the prior art. Schlegel et al. (US 2007/0142459 A1) claims generally the treatment of viral infections, including hepatitis virus infections, by administering artemisinin. However, Schlegel et al. fail to teach or suggest the particular activities of artemisinin, and its derivatives herein against BVDV and HCV.

The examiner tried to contact applicants' attorney, Mr. Kent A. Herink, to resolve the 112 issues in the pending claims, but without success.

Following subject matter would be allowable:

A method of treating an infection caused by *Flaviviridae sp.* comprising the step of administering an effective amount of a *sesquiterpene* having the formula:



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wherein:

X1 and X2 are O;

Y is O;

Z is O;

Q is selected from the group consisting of CO, CHOH, CHOCH<sub>3</sub>, CHOC<sub>2</sub>H<sub>5</sub>, CHOC<sub>3</sub>H<sub>7</sub>, and CHOCOCCH<sub>2</sub>COOH, and the pharmaceutically acceptable salts thereof; and wherein the infection is hepatitis C or bovine viral diarrhea.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shengjun Wang/  
Primary Examiner, Art Unit 1627

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